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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,600	08/26/2003	Jerome R. Edwards	JRME:001US	4961

22903 7590 06/01/2006

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WASHINGTON, DC 20005-2221

EXAMINER
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CHENG, JACQUELINE

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/649,600	<b>Applicant(s)</b> EDWARDS, JEROME R.	
	<b>Examiner</b> Jacqueline Cheng	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/8/05 8/4/04 2/04</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-40 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,246,898 B1 (herein referred to as Vesely et al.).

3. **Claims 1-7, 13-20, 24-37, 39:** Vesely et al. discloses carrying out a medical procedure using a 3-D tracking and imaging system. A surgical instrument such as a catheter is inserted into a living being and the position of the instrument is tracked as it moves through the body. A plurality of mobile transducers are fitted to the instrument, as well as one or more reference transducers that provide a reference position relative to the mobile transducers. These reference transducers may be located internally or externally. The transducers are then tracked using an imaging modality system such as fluoroscopy, MRI or CT creating a 2D or 3D image data set. An image registration system then registers the position of the instrument within the spatial coordinates of the image data set provided by the imaging modality system. This system provides a display of the instrument at its proper transformed location inside the body in accordance to the reference transducers image data coordinates (col. 13 line 16-col. 14 line 12). One of the most critical aspects of the 3D image is this correct spatial relationship of the instrument with the underlying images showing the environment surrounding the instrument (col.

16 line 33-52). Information from the mobile transducers on the instrument, from the other internally placed transducer in the region, and from the external reference transducers can be translated into vector data which in turn can be used to illustrate the position and the direction of the tip (col. 21 line 11-19).

4. **Claims 8-12:** Vesely et al. discloses that these dataset images, of areas such as the heart itself, can be synchronized with a patient's heartbeat. A raw ECG signal is inputted into a processing computer that processes the data and produces a timing signal that corresponds to the activity of the heart. The processing computer follows the input signal and compares it to information relevant to the expected morphology of the signal (such as matching the signals of a previous ECG signal) and tests for large rates of change in the signal (col. 16 line 61-col. 17 line 10). The images can then be viewed with the external reference transducer and the internal mobile transducer.

5. **Claims 21 and 22:** Vesely et al. discloses imaging and determining the positions of the reference transducer (external reference marker), internally placed reference transducers (internal non-tissue reference marker), and the mobile transducer (instrument reference marker). The tracking space coordinates of the mobile transducer are registered as well as trying to match them to the reference transducers coordinates. These matched coordinates from the instrument reference marker and the reference markers in the image are then overlaid on top of each other (col. 16 line 33-52), (col. 21 line 11-19).

6. **Claim 23, 38, and 40:** The system of Vesely includes a computer with computer readable medium and machine readable instruction (computer system, element 1620).

***Conclusion***

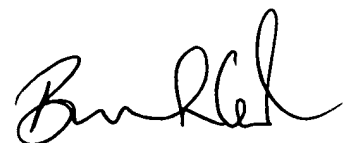
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,484,049 B1, Seeley et al., discloses a tracker of an instrument with using implanted fiducials and adding externally visible or trackable markers used in fluoroscopic, MRI or CT images. US Patent No. 5,644,612, Moorman et al., discloses a reference marker on the catheter and a system that is gated to the cardiac cycle.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC



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